2018 Current Fiscal Year Report: Science Advisory Board to the National Center for Toxicological Research

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1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2018

3. Committee or Subcommittee	3b. GSA Committee No.
Science Advisory Board to the National Center for Toxicological Research	1023

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	06/02/2018	06/02/2020	

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
No		

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Continue	Not Applicable	Not Applicable

11. Establishment Authority Authorized by Law

12. Specific Establishment Authority	13. Effective Date	14. Commitee Type	14c. Presidential?
21 U.S.C. 394	11/28/1990	Continuing	No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports No Reports for this FiscalYear

17a. Open 0 **17b. Closed** 0 **17c. Partially Closed** 1 **Other Activities** 0 **17d. Total** 1

Meetings and Dates

Purpose	Start	End
During FY2018 there was one two day meeting of the full board. On November 6-7, 2017, the National Center for Toxicological Research Director welcomed the participants and provided a Center-wide update on scientific initiatives and accomplishments during the past year. The Science Advisory Board was presented with an overview of the Division of Systems Biology Subcommittee and the Subcommittee Site Visit Report and a response to the review.	11/06/2017	11/07/2017

Number of Committee Meetings Listed: 1

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$11,001.00	$12,031.00
18a(2). Personnel Pmts to Federal Members	$0.00	$0.00
18a(3). Personnel Pmts to Federal Staff	$159,075.00	$162,438.00
18a(4). Personnel Pmts to Non-Member Consultants	$3,194.00	$2,187.00
18b(1). Travel and Per Diem to Non-Federal Members	$8,797.00	$8,426.00

18b(2). Travel and Per Diem to Federal Members	$0.00	$0.00
18b(3). Travel and Per Diem to Federal Staff	$2,164.00	$2,176.00
18b(4). Travel and Per Diem to Non-member Consultants	$4,080.00	$2,018.00
18c. Other(rents,user charges, graphics, printing, mail, etc.)	$47,858.00	$48,781.00
18d. Total	$236,169.00	$238,057.00
19. Federal Staff Support Years (FTE)	0.80	0.80

20a. How does the Committee accomplish its purpose?

The National Center for Toxicological Research (NCTR) Science Advisory Board (SAB) advises the Director in establishing, implementing and evaluating the research programs that assist the Commissioner of the Food and Drug Administration (FDA) in fulfilling regulatory responsibilities. This external body of recognized scientific experts is a key component of the review and planning process, and helps to ensure that the research programs at NCTR are scientifically sound and pertinent to the FDA.

20b. How does the Committee balance its membership?

Members are leading authorities in the fields related to toxicological research. Members represent academia, clinical research, and other scientific disciplines.

20c. How frequent and relevant are the Committee Meetings?

It is likely that the Board will hold one site visit and one meeting of the full Board in FY-2019.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

This function could be performed on an ad hoc basis, however, it would be a much more costly process than what is currently being spent using SGEs. There would be no reduction in alotted Federal staff time, since that time would still be required to support the ad hoc review activity. Moreover, utilizing an ad hoc review approach would not permit the seamless evaluation of the total NCTR research agenda, the inter-relationships of its research components, and the long-range impact on the FDA mission.

20e. Why is it necessary to close and/or partially closed committee meetings?

The Board meets in closed session to permit disucssion where disclosure would constitute a clearly unwarrented invasion of personal privacy (5 U.S.C. 522b(c)(6)). These portions of the meetings are closed to permit discussion of issues related to personnel progress and promotion.

21. Remarks

During FY18 there was one two-day meeting of the full board. On November 6-7, 2017, the NCTR Director welcomed the participants and provided a Center-wide update on scientific initiatives and accomplishments during the past year. The SAB was presented with an overview of the Division of Systems Biology Subcommittee and the Subcommittee Site Visit Report and a response to the review.

Designated Federal Officer

Donna L. Mendrick Associate Director for Regulatory Activities, Washington Operations, NCTR

Committee Members	Start	End	Occupation	Member Designation
ASCHNER, MICHAEL	08/22/2017	06/30/2021	Professor of Molecular Pharmacology	Special Government Employee (SGE) Member
Felter, Susan	09/29/2014	06/30/2019	Proctor & Gamble	Special Government Employee (SGE) Member
Jain, Diwakar	09/30/2014	06/30/2018	New York Medical College	Special Government Employee (SGE) Member
Kaspar, Charles	07/01/2018	06/30/2022	University of Wisconsin	Special Government Employee (SGE) Member
Lanza, Gregory	05/31/2016	06/30/2020	Washington University School of Medicine	Special Government Employee (SGE) Member
Lein, Pamela	09/29/2014	06/30/2019	UC Davis School of Vet. Medicine	Special Government Employee (SGE) Member
Ramos, Kenneth	04/20/2018	06/30/2022	Assoc. Vice President	Special Government Employee (SGE) Member
Stice, Steven	05/31/2016	06/30/2020	University of Georgia	Special Government Employee (SGE) Member

Number of Committee Members Listed: 8

Narrative Description

FDA’s strategic priorities in responding to the public health challenges of the 21st century are to advance regulatory science and innovation; strengthen the safety and integrity of the global supply chain; strengthen compliance and enforcement activities to support public health; expand efforts to meet the needs of special populations; advance medical countermeasures and emergency preparedness; advance food safety and nutrition; promote public health by advancing the safety and effectiveness of medical products; establish an effective tobacco regulation, prevention, and control program; and manage for organizational excellence and accountability. The Science Advisory Board to the National Center for Toxicological Research supports FDA's strategic priorities by establishing, implementing and evaluating the research programs that assist the Commissioner of Food and Drugs in fulfilling her regulatory responsibilities. The Board provides an extra-agency review in ensuring that the research programs at NCTR are scientifically sound and pertinent to the mission of the FDA.

What are the most significant program outcomes associated with this committee?

	Checked if Applies
Improvements to health or safety	✓
Trust in government	✓
Major policy changes	✓
Advance in scientific research	✓
Effective grant making	
Improved service delivery	
Increased customer satisfaction	✓
Implementation of laws or regulatory requirements	✓
Other	

Outcome Comments

NA

What are the cost savings associated with this committee?

	Checked if Applies
None	
Unable to Determine	✓
Under $100,000	
$100,000 - $500,000	
$500,001 - $1,000,000	
$1,000,001 - $5,000,000	
$5,000,001 - $10,000,000	
Over $10,000,000	
Cost Savings Other	

Cost Savings Comments

The utilization of the Science Advisory Board to the National Center for Toxicological Research enables the Agency to obtain required and frequently scarce professional services from medical and scientific experts not otherwise available to the Agency; and to obtain the services of these experts not otherwise available to the Agency; and to obtain the services of these experts only on an as needed basis rather than on a full time basis. The service of the Committee resulted in advice for the improvement of the public health, for which it is difficult to assign a financial value.

What is the approximate Number of recommendations produced by this committee for the life of the committee?

27

Number of Recommendations Comments
The committee made 27 recommendations from FY-03 through FY-18. See 20a of the annual report for specific accomplishments.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?
78%

% of Recommendations Fully Implemented Comments
The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature,and therefore, the Agency has the option of not implementing the advice.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?
7%

% of Recommendations Partially Implemented Comments
The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?
Yes ☑ No ☐ Not Applicable ☐

Agency Feedback Comments
It usually does. Product approval issues are first released to the sponsor. When appropriate, information is made available to the public. Actions related to guidance documents or other general matters issues are available publicly when implemented.

What other actions has the agency taken as a result of the committee's advice or recommendation?

	Checked if Applies
Reorganized Priorities	☑
Reallocated resources	☐
Issued new regulation	☑

Proposed legislation	☐
Approved grants or other payments	☐
Other	✓

Action Comments

FDA approves or chooses not to approve new medical product.

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

NA

How is access provided to the information for the Committee's documentation?

	Checked if Applies
Contact DFO	✓
Online Agency Web Site	✓
Online Committee Web Site	☐
Online GSA FACA Web Site	✓
Publications	✓
Other	☐

Access Comments

NA